Millar INSTRUMENTS

AT THE HEART OF SENSOR INNOVATION®

JAN - 5 2010

2.0 510K Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR807.92.

The assigned 510(k) number is: K09311

Date: 12/02/2009

Organization Number: 211571

Establishment: Millar Instruments, Inc.

Owner Name: Huntly Millar

Address: 6001-A Gulf Freeway, Houston, TX 77023

Phone: 832-667-7000

Fax: 832-667-7001

Registration Number: 1625382

Operations: Specification Developer and Manufacturer of Mikro-Tip Catheter Transducers and Accessories for Clinical and Research purposes.

Contact: Fatma Ali, Director of Regulatory Affairs and Quality Assurance

Name of the Devices: Mikro-Cath

Common Name: Mikro-Cath

Classification Name: Transducer, Pressure, Catheter Tip

Regulation: Catheter Tip Pressure Transducer (21 CFR 870-2870)

Product Code : DXO

Device Description: The Mikro-Cath is a disposable/single use, sterile cardiovascular pressure catheter transducer for monitoring and measuring pressure anywhere in the cardiovascular system with an appropriately sized guide catheter.

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Intended Use: Millar Mikro-Cath will be used to measure hemodynamic cardiac pressures in the human body to allow physicians to better understand cardiovascular health. It will be used as a minimally invasive device under short term limited body contact <24 hours. The typical application will be through the femoral artery with the use of an additional guiding catheter.

Comparison to the Predicate Device(s): Millar Mikro-Cath is substantially equivalent in performance and intended use to Millar Cardiovascular Mikro Tip Catheter Transducer Model SPC-330A approved device (reference Millar 510K# K792177). Mikro-Cath is a single use sterile device. Same accessories of the predicate devices will be used for Mikro-Cath.

- M.I. P/N: 880-0129, Model PCU-2000 Control Unit with Patient Isolation
- M.I. P/N: 850-1308, Model TEC-10D Extension Cable to TC-510 or TCB-500
- M.I. P/N: 850-5103, Model PEC-4D Extension Cable to PCU-2000
- M.I. P/N: 850-5090, Model PEC-10D Extension Cable to PCU-2000

All accessories are previously approved with Millar Device Model PCU-2000(reference 510K#: K013205)

- Millar Mikro-Cath is substantially equivalent in packaging and sterilization to Millar Angiographic Catheter single use sterile device. Model SPC-454D approved device under Millar 510K# K952773

- Millar Mikro-Cath is substantially equivalent in design and material with Millar VPM-10 (Codman & Shurtleff Inc. Microsensor Intracranial Pressure Transducer 510K # 914479.

Discussion of Non-clinical Tests performed:

- Biocompatibility, sterility, Electromagnetic Compatibility (EMC), Packaging Accelerating/Aging and performance testing are conducted in accordance with the applicable standards listed below for the type of testing.
  - Performance testing in accordance with AAMI ANSI BP22:1994 (R) 2006
  - Biocompatibility testing in accordance with ISO 10993-1:2003
  - Sterility validation testing in accordance with ISO 11135-1:2007
  - EMC testing in accordance with EN 60601-1-2:2007
  - Packaging Accelerating/Aging testing in accordance with ASTM F1980 (Standard Guide for Accelerated Aging of Sterile Medical Device Packages) and ISO 11607 (Packaging for Terminally Sterilized Medical Devices).

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- **Conclusion:**

The Millar Mikro-Cath has the same intended use as the approved devices previously marketed by Millar for Cardiovascular monitoring applications.
The performance testing meets the applicable standard AAMI ANSIBP22:1994 (R) 2006 for Blood Pressure Transducers and therefore maintain the same levels of safety and effectiveness as the predicate devices currently in commercial distribution.

6001-A Gulf Freeway Houston, Texas 77023-5417 Phone 832.667.7000 Fax 832.667.7001 Within the USA 800.669.2363 www.millarinstruments.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Millar Instruments, Inc.
c/o Ms. Fatma Ali
Director of Regulatory Affairs and Quality Assurance
6001-A Gulf Freeway
Houston, TX 77023

Re: K093111
Trade/Device Name: Mikro-Cath, Model 825-0101
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter Tip Pressure Transducer
Regulatory Class: Class II (two)
Product Code: DXO
Dated: December 2, 2009
Received: December 8, 2009

Dear Ms. Ali:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

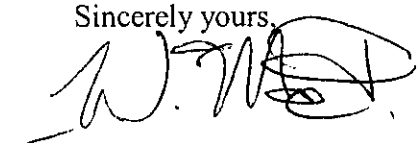
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093111

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1.0 Indications for Use Statement

The Mikro-Cath is a single-use cardiovascular catheter intended to be used for medical research and diagnostic purposes. The catheter is used to measure hemodynamic cardiac pressures in the human body to allow physicians to better understand cardiac health. The catheter would be used as a minimally invasive device under short term limited body contact <24 hours. The typical application will be through the femoral artery with the use of an additional guiding catheter.

Prescription Use:____X____ and/or Over-the-Counter Use: _____

(Part 21CFR801 Subpart D) (Part 21CFR801 Subpart C)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093111

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